

authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 520 is amended as follows:

#### **PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS**

1. The authority citation for 21 CFR part 520 continues to read as follows:

**Authority:** Sec. 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b).

2. Section 520.1263c is amended by revising paragraph (a) to read as follows:

#### **§ 520.1263c Lincomycin hydrochloride soluble powder.**

(a) *Specifications.* Each 40-gram packet (1.41 ounce) contains lincomycin hydrochloride equivalent to 16 grams of lincomycin. Each 80-gram packet (2.82 ounces) contains lincomycin hydrochloride equivalent to 32 grams of lincomycin.

\* \* \* \* \*

Dated: March 8, 1995.

**Robert C. Livingston,**

*Director, Office of New Animal Drug  
Evaluation, Center for Veterinary Medicine.*

[FR Doc. 95-6531 Filed 3-15-95; 8:45 am]

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#### **21 CFR Part 520**

#### **Oral Dosage Form New Animal Drugs; Neomycin Sulfate Soluble Powder**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule.

**SUMMARY:** The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of an abbreviated new animal drug application (ANADA) filed by Sanofi Animal Health, Inc. The ANADA provides for the use of a generic neomycin sulfate soluble powder administered orally in drinking water or in milk for the treatment and control of colibacillosis in cattle (excluding veal calves), swine, sheep, and goats.

**EFFECTIVE DATE:** March 16, 1995.

**FOR FURTHER INFORMATION CONTACT:** Melanie R. Berson, Center for Veterinary Medicine (HFV-135), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-594-1643.

**SUPPLEMENTARY INFORMATION:** Sanofi Animal Health, Inc., 7101 College Blvd., suite 610, Overland Park, KS 66210, filed ANADA 200-050, which provides for the oral use of neomycin sulfate soluble powder in drinking water or milk for cattle (excluding veal calves), swine, sheep, and goats for the

treatment and control of colibacillosis (bacterial scours) caused by *Escherichia coli* susceptible to neomycin sulfate.

Approval of ANADA 200-050 is as a generic copy of The Upjohn's approved NADA 11-315 for Neomix® 325 soluble powder. The ANADA is approved as of February 15, 1995, and the regulations are amended by revising § 520.1484(b) (21 CFR 520.1484(b)) to reflect the approval. The basis for approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of part 20 (21 CFR part 20) and § 514.11(e)(2)(ii) (21 CFR 514.11(e)(2)(ii)), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

#### **List of Subjects in 21 CFR Part 520**

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 520 is amended as follows:

#### **PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS**

1. The authority citation for 21 CFR part 520 continues to read as follows:

**Authority:** Sec. 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b).

2. Section 520.1484 is amended by revising paragraph (b) to read as follows:

#### **§ 520.1484 Neomycin sulfate soluble powder.**

\* \* \* \* \*

(b) *Sponsors.* See Nos. 000009, 000069, 050604, and 059130 in § 510.600(c) of this chapter.

\* \* \* \* \*

Dated: March 8, 1995.

**Stephen F. Sundlof,**

*Director, Center for Veterinary Medicine.*

[FR Doc. 95-6530 Filed 3-15-95; 8:45 am]

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#### **21 CFR Part 522**

#### **Implantation or Injectable Dosage Form New Animal Drugs; Oxytetracycline Injection**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule.

**SUMMARY:** The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of an abbreviated new animal drug application (ANADA) filed by Phoenix Scientific, Inc. The ANADA provides for the use of oxytetracycline injection in cattle and swine for the treatment of diseases caused by oxytetracycline susceptible organisms.

**EFFECTIVE DATE:** March 16, 1995.

**FOR FURTHER INFORMATION CONTACT:** Melanie R. Berson, Center for Veterinary Medicine (HFV-135), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-594-1643.

**SUPPLEMENTARY INFORMATION:** Phoenix Scientific, Inc., 3915 South 48th Street Terrace, P.O. Box 6457, St. Joseph, MO 64506-0457, has filed ANADA 200-123 which provides for use of oxytetracycline injection as follows: (1) Intramuscular or intravenous use in beef and nonlactating dairy cattle for the treatment of pneumonia and shipping fever associated with *Pasteurella* spp. and *Hemophilus* spp.; infectious bovine keratoconjunctivitis (pinkeye) caused by *Moraxella bovis*; foot rot and diphtheria caused by *Fusobacterium necrophorum*; bacterial enteritis (scours) caused by *Escherichia coli*; wooden tongue caused by *Actinobacillus lignieresii*; leptospirosis caused by *Leptospira pomona*; and wound infections and acute metritis caused by strains of staphylococci and streptococci organisms sensitive to oxytetracycline; (2) intramuscular use in swine for treatment of bacterial enteritis (scours, colibacillosis) caused by *E. coli*; pneumonia caused by *P. multocida*; and leptospirosis caused by *L. pomona*; and (3) intramuscular use in sows for control of infectious enteritis (baby pig scours, colibacillosis) in suckling pigs caused by *E. coli*.

Phoenix Scientific's ANADA 200-123 for oxytetracycline injection (Maxim 200) is approved as a generic copy of Pfizer's NADA 113-232 for oxytetracycline injection (Liquamycin®).

LA-200). The ANADA is approved as of February 10, 1995, and the regulations are amended in 21 CFR 522.1660(b) and (c)(2)(iii) to reflect the approval. The basis for approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of part 20 (21 CFR part 20) and § 514.11(e)(2)(ii) (21 CFR 514.11(e)(2)(ii)), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

#### List of Subjects in 21 CFR Part 522

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 522 is amended as follows:

#### PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 522 continues to read as follows:

**Authority:** Sec. 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b).

2. Section 522.1660 is amended in paragraph (b) by removing the phrase "000010 and 000069" and adding in its place "000010, 000069, and 059130", and in paragraph (c)(2)(iii) by revising the last sentence to read as follows:

#### § 522.1660 Oxytetracycline injection.

\* \* \* \* \*

(c) \* \* \*

(2) \* \* \*

(iii) \* \* \* Discontinue treatment at least 42 days prior to slaughter when provided by 000010 and 28 days prior to slaughter when provided by 000069 or 059130.

Dated: March 8, 1995.

**Stephen F. Sundlof,**

*Director, Center for Veterinary Medicine.*

[FR Doc. 95-6527 Filed 3-15-95; 8:45 am]

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## DEPARTMENT OF LABOR

### Occupational Safety and Health Administration

#### 29 CFR Part 1915

[Docket No. S-050]

#### Confined and Enclosed Spaces and Other Dangerous Atmospheres in Shipyard Employment

**AGENCY:** Occupational Safety and Health Administration (OSHA), Department of Labor.

**ACTION:** Final rule; correction.

**SUMMARY:** In the July 25, 1994, **Federal Register** OSHA published a revised standard for Shipyard Employment, subpart B of 29 CFR part 1915, extending the previous requirements for work in explosive and other dangerous atmospheres on ships to cover all work involving confined or enclosed spaces or other dangerous atmospheres throughout shipyard employment (59 FR 37816). With the present document, OSHA is making corrections to the rule which include: clarifying the order of testing before employees may enter a confined or enclosed space or other dangerous atmosphere; clarifying when flammable atmospheres must be maintained above the upper explosive limit during installation of ventilation or rescue; and clarifying the limited locations and conditions where hot work may be performed without first being certified by a Marine Chemist. Several typographical errors are also being corrected.

**EFFECTIVE DATE:** The final rule published on July 25, 1994, became effective on October 24, 1994. These corrections are effective March 16, 1995.

#### FOR FURTHER INFORMATION CONTACT:

Richard Liblong, Director, Office of Information and Consumer Affairs, Occupational Safety and Health Administration, Room N3647, U.S. Department of Labor, 200 Constitution Ave., N.W., Washington, D.C. 20210 (202-219-8148).

#### SUPPLEMENTARY INFORMATION:

#### I. Correction to § 1915.12—Precautions Before Entering Confined and Enclosed Spaces and Other Dangerous Atmospheres

OSHA is correcting the section heading to § 1915.12 to make clearer the requirement that atmospheric testing must be done in the order set forth in the standard (i.e., oxygen content, then flammability, and then toxicity).

In the preamble to the final rule OSHA explained how the section was being reformatted to address the order of atmospheric testing to be conducted when determining hazards within confined and enclosed spaces and other dangerous atmospheres prior to entry (59 FR 37830). The Agency stated explicitly in the preamble to paragraphs (a), (b), and (c) of § 1915.12 that atmospheres must be tested for oxygen content first, flammability second, and toxicity third (59 FR 37831). However, the section heading did not include the sequence of testing, and the specific introductory statement requiring atmospheric testing to be conducted in the proper sequence was inadvertently omitted from the regulatory text. The insertion of the sequence of testing into the section heading and the addition of the introductory text to § 1915.12 brings the section into conformance with the rulemaking record, the preamble explanation, and OSHA's intent.

#### II. Correction to § 1915.12(b)—Flammable Atmospheres

In the previous standard covering entry into spaces containing flammable atmospheres, § 1915.12(d), employees were allowed to perform work of brief duration in atmospheres containing concentrations of flammable contaminants as long as the concentrations remained above the upper explosive limit (UEL) and the requirements of § 1915.152(a) and (b), *Respiratory protection*, were followed. That allowance was continued in the proposed revision to subpart B, § 1915.12(d), *Work of brief duration* (53 FR 48108). In the final standard, which permits such entry only to set up ventilation or for rescue, OSHA carried over the condition that the flammable contaminant(s) be maintained above the UEL (59 FR 37858). Unfortunately, the wording of this condition could be construed to require that levels of atmospheric contaminants in a space actually be increased to a level above the UEL prior to ventilation start-up or rescue so that they may be maintained above the UEL. OSHA did not intend the rule to require this. When the atmosphere is below the UEL (but above